CLAIMS

1- Use of polymers derived from vinyl acetate in pharmaceutical solid forms characterized by

- use of polyvinylacetate of mean molecular weight between 10000 and 40000 daltons, remnant monomer content less than 2 ppm by weight, water content less than 1.5 % by weight, total acidity referred to acetic acid less than 0,5 % by weight, peroxide content 0,0 %, glass transition temperature 35-39 °C, innocuous after oral ingestion;

- use of copolymers of vinylacetate-vinyl alcohol with less than 30 % vinyl alcohol monomeric units content and the same vinylacetate and water content as above describes for polyvinylacetate.

2- Procedure for the obtaining of polyvinylacetate, with mean molecular weight, the purity requirements and innocuousness describes under Claim 1, by polymerization of vinyl acetate in solution, preferably in ethanol, with use of dibenzoyl peroxide as initiator, subjected to a preliminary purification step by means of the addition of an adequate volume of hot water to a solution of the polymer (in ethanol or other volatile solvent), or by means of the addition of a solution of the polymer to an adequate volume of hot water (> 80 °C), during a time that depends on the employed equipment, on the mechanical stirring, and on the maintenance of a high temperature (> 80 °C) of the resultant mass, with optionally bubbling of purified air through the said mass, until the achievement of the separation of the solvent by means of evaporation or dragging with help of the water vapor, the decomposition of the remnant initiator, the dissolution of the major part of the benzoic acid in water and the removal of the major part of the remnant monomer, the separation of the water phase from the semisolid humid polymer mass and the further purification of the said semisolid mass, being this purification and the handling of the final product characterized by

- heating of the said mass at a temperature between 80 and 140 °C, under vacuum (0.02-13 kPa), and stirring the mass slowly until the polymer presents the desired purity and dryness;
- evacuating molten the purified polymer from the purification equipment.

3- Procedure for the obtaining of vinyl acetate-vinyl alcohol copolymers with the characteristics describes under Claim 1 by means of alkaline alcoholysis/hydrolysis of polyvinylacetate of high purity, characterized by

- the use of an alcohol, preferably ethanol, as solvent, and the fixing of a ratio between the initial quantities (by weight) of polyvinylacetate/alcohol/alkaline hydroxide within the range of ratios that, following the same order, is expressed in the ratio: 50-80 /130-170/ 1;
- the addition of water to the initial reaction mixture in such quantities that it constitutes between 4 and 25% by volume of the solvent present;
- being performed the final purification of the copolymer in similar way as is describes under Claim 2.

4- Procedure for the obtaining of polyvinylacetate and of vinyl acetate- vinyl alcohol copolymers as a powder, stable enough in its storage and useful in preparations of compressed tablets obtained by direct compression or by means of previous wet granulation, characterized by

- use of polyvinylacetate with mean molecular weight, the purity requirements and innocuousness describes under Claim 1, as starting material;
- being performed the procedure in three steps, the first of which is the milling of the said polymer in a cutting or hammer mill, using a sieve with hole dimensions between 2.5 and 0.8 mm; the second step is the mixing of the gross grained polymer, obtained in the describes first step, with pharmaceutical crystalline excipients of small particle size (preferably lactose) or with a crystalline active substance, being the said substance 30-80 weight % of the total mixture, followed by the milling of the mixed solid in the same kind of mill using a sieve with hole dimensions between 0.2 and 0.04 mm; the third step is the homogenizing mixing of the milled product.

5- Procedures for use of polyvinylacetate as binder in base granulates or of granulates that contain active substances, being the said procedures characterized by

- use of polyvinylacetate with mean molecular weitht, the purity requirements, dryness and innocuousness described under Claim 1, as the only or principal binder;
- use of said polyvinylacetate as solid powder intimately mixed with lactose or with other crystalline excipient, obtained by the procedure described under Claim 4, for the obtaining of granulates by means of moistening with acetone, ethanol or other appropriate solvent, or use of said polymer in a solution with an organic convenient solvent.
- use of said polyvinylacetate in a quantity that represents between 1 and 10% by weight of dried granulates.

6- Procedures for use of polyvinylacetate or vinyl acetate-vinyl alcohol copolymers with mean molecular weight, the purity requirements, dryness and innocuousness describes under Claim 1 as simultaneous binders and sole or main constituents of release controlling matrixes (> 60 weight % of the polymeric matrix and between 2 and 25 weight % of the pharmaceutical solid form) in compressed tablets and pellets being the said procedures characterized by the fact that the occlusion of the active substance, the drug or the releasing substance in general, within the matrixes of the said polymers takes place by either one of the following ways;

- depositing the polymer on one, several or all the components of the formulation by wetting them with a polymer solution, evaporating thereafter the solvent, granulating and optionally compressing the mixture with addition or not of other excipients as fillers or lubricants,

- intimate mixing of the polymer as powder or as granulate, obtained by the procedure describes under Claim 4, with active substance or drug, solid or liquid, supported in the latter case on an inert solid, granulating the mixture if necessary by means of humectation with a solvent of the polyvinylacetate and compressing the said mixture with addition or not of other excipients as fillers or lubricants.